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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,981	06/29/2006	Keyvan Behnam	2004367-0078	2245

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,981	BEHNAM ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of 1/13/2009 was fully responsive to the original restriction requirement. However, upon reconsideration, the restriction requirement, based on a holding of lack of unity of invention, has been revised. The following restriction requirement is intended to **REPLACE** all prior restriction requirements:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 31-46 and 48, drawn to a first product: a modified bone matrix, comprising a bone matrix that has been exposed to a treatment or condition that increases at least one biological activity of the bone matrix relative to an untreated bone matrix.

Group 2, claim(s) 1-27 and 29, drawn to a method of making the first product.

Group 3, claim(s) 28, 30 and 47, drawn to a method of using the first product.

Group 4, claim(s) 52 and 53, drawn to a second product: a cell composition comprising cells and a modified bone matrix.

Group 5, claim(s) 49, drawn to a method of making the second product.

Group 6, claim(s) 50, drawn to a method of using the second product.

Group 7, claim(s) 54-58 and 60, drawn to a third product: a modified bone matrix, comprising a collagen-containing bone matrix wherein at least a portion of the collagen is cleaved or degraded.

Group 8, claim(s) 59, drawn to a method of using the third product.

Group 9, claim(s) 61-63 and 65, drawn to a fourth product: a modified bone matrix, comprising a collagen-containing bone matrix wherein at least a portion of an inhibitor of osteoinductive, osteogenic or chondrogenic activity is cleaved or degraded.

Group 10, claim(s) 64, drawn to a method of using the fourth product.

Group 11, claim(s) 66-71, drawn to a fifth product: a human demineralized bone matrix (DBM) having increased solubility.

Group 12, claim(s) 72, drawn to a method of making the fifth product.

The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature which links Groups 1-6 is considered to be a modified bone matrix comprising a bone matrix that has been exposed to a treatment or condition that increases at least one biological activity of the bone matrix relative to an untreated bone matrix (represented by claim 31).

However, claim 31, at least, is anticipated by Nashef et al (US Patent 4,678,470). Nashef et al disclose bone material which has been modified by treatment with an organic solvent; the treated bone has increased porosity, which encourages bony ingrowth (which is considered an increase in a biological activity) (See Nashef et al, col. 3, ln 47-col. 4, ln 2). Consequently, the special technical feature which links the claims of Groups 1-6, does not provide a contribution over the prior art, so unity of invention is lacking.

The claims of Groups 7-12 lack this feature entirely, so there is no unity of invention between the claims of Groups 1-6 and the claims of Groups 7-12.

The special technical feature which links Groups 7-10 is considered to be a modified bone matrix comprising a collagen-containing bone matrix, wherein at least one component of the bone matrix has been cleaved or degraded (represented by claims 54 and 61).

However, at least claim 54 and claim 61 are anticipated, again, by Nashef et al. Nashef et al disclose bone material which has been treated with a collagenase (See Nashef et al, col. 3, ln 54-63). Collagenase cleaves and degrades at least some collagen which is present within the bone matrix. Collagen can be considered an inhibitor of osteogenesis and osteoinduction because its mere presence within a bone matrix precludes cell growth in that same space. Consequently, the special technical feature which links the claims of Groups 7-10 does not provide a contribution over the prior art, so unity of invention is lacking.

The claims of Groups 1-6 and 11-12 lack this feature entirely, so there is no unity of invention between the claims of Groups 1-6, 11 and 12 and the claims of Groups 7-10.

The special technical feature which links Groups 11 and 12 is considered to be a human demineralized bone matrix with increased solubility over that of normal human demineralized bone matrix (represented by claim 66).

However, claim 66 is unpatentable over the teachings of O'Leary et al (US Patent 5,073,373). O'Leary disclose demineralized bone matrix which has been pulverized to a powder which may be combined with an liquid carrier (See O'Leary et al, Example spanning col. 4-5). The reduced size of the bone material increases its solubility, at least compared to untreated bone. Though O'Leary et al do not state human DBM may be used, O'Leary et al does state allogenic bone is desired (See col. 2, ln 12-13), thus in the case of treatment of a human, allogenic *human* bone would be the desired source. Thus, demineralized human bone matrix which has increased solubility compared to untreated human DBM fails to provide a contribution over the art, and thus unity of invention is lacking.

The claims of Groups 1-10 lack this feature entirely, so there is no unity of invention between the claims 1-10 and the claims of Groups 11-12.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all

criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651